STERIS®

AUG 07 2009

510(k) Summary
For
Verify® 275F Gravity Indicators

STERIS Corporation
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Contact: Robert F. Sullivan.
Senior Director, FDA Regulatory Affairs

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Summary Date: August 5, 2009

1. Device Name

Indicators Models:	Verify® 275F 3-10 Indicator. Verify® 275F 10 Indicator.
Common Name:	Chemical Indicators.
Classification Name:	Physical/chemical sterilization process indicators (21 CFR 880.2800 (b), Product Code JOJ).

2. Predicate Devices

- DANA SteriScan Indicators (K012195)
- SteriTec Integraph [Cardinal Steam Integrators[1] (K960441)]
- STERIS Verify Integrators (K002937)

3. Device Description

The proposed Verify® 275F Gravity Indicators consist of:

- A 22 mm x 143 mm polypropylene strip with two 12 mm chemical indicator ink spots (for Verify® 275F 3-10 Indicator).
- A 22 mm x 143 mm polypropylene strip with one 12 mm chemical indicator ink spots (for Verify® 275F 10 Indicator).

The indicator ink spots are located on each end of the strip (or one end if it is just one ink spot), adjacent to a reference block exhibiting the endpoint color. The indicator ink on the proposed Verify® 275F Gravity Indicators changes from yellow to blue/purple color when the steam sterilization cycle is complete.

The Verify® 275F Gravity Indicators can be used to monitor 275°F (135°C) sterilization cycles as follows:

- The Verify® 275F 3-10 Indicator can be used to monitor a 3 and 10 minute 275°F (135°C) gravity flash steam sterilization cycle.
- The Verify® 275F 10 Indicator can be used to monitor a 10 minute 275°F (135°C) gravity steam sterilization cycle.

[1] Cardinal is a private label brand produced by Steritec under K960441.

4. Intended Use

The Verify® 275F Gravity Indicators are chemical indicators intended for use by health care providers to accompany products being sterilized through a sterilization procedure. The indicators change color from yellow to blue/purple when exposed to saturated steam at 275°F for the specified period of time. The performance of the Verify® 275F Gravity Indicators meet the requirements of ANSI/AAMI / ISO 11140-1:2005 for emulating [Class 6] chemical steam indicators.

5. Description of Safety and Substantial Equivalence

The proposed and predicate devices are all single use indicators for use in steam sterilization cycles. The differences between the proposed Verify® 275F Gravity Indicators and predicate devices are limited to differences in design, material, and parameters of the sterilization cycles these indicators are designed to monitor. These differences do not raise any new issues of safety and efficacy.

6. Performance Testing

Performance testing was conducted to verify that the proposed Verify® 275F Gravity Indicators meet the requirements for emulating [Class 6] chemical indicators as defined in ANSI/AAMI ISO 11140-1:2005 using a resistometer to ANSI/AAMI ISO 18472.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

AUG 07 2009

Mr. John R. Scoville
Senior Director of FDA Regulatory Affairs
STERIS Corporation
5960 Heisley Road
Mentor, Ohio 44060-1834

Re: K083643
Trade/Device Name: Verify® 275F Gravity Indicators
Regulation Number: 21 CFR 880. 2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: JOJ
Dated: July 9, 2009
Received: July 14, 2009

Dear Mr. Scoville:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Susan Runner, D.D.S., M.A.
Acting Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083643

Device Name: Verify® 275F Gravity Indicators

Indications for Use:

The Verify® 275F Gravity Indicators are chemical integrators which meet ANSI/AAMI 1140-1:2005 for emulating indicators intended for use in steam sterilization. The Verify® 275F Gravity Indicators change color from yellow to blue/purple when exposed to 275°F (135°C) and to the appropriate cycle type and duration. The Verify® 275F Indicators models and their cycle types and times are:

MODEL	TEMPERATURE	STERILIZATION TYPE	TIME
Verify 275F 3-10	275°F (135°C)	Gravity flash steam	3 and 10 minutes
Verify 275F 10	275°F (135°C)	Gravity steam	10 minutes

Prescription Use _____ AND/OR Over-The-Counter Use __X__
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K083643

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